REMARKS

Claims 1-36 remain pending, with claims 1-11 and 14-35 withdrawn from consideration as being directed to a non-elected invention. By the foregoing amendment, claims 12, 14, 17, and 20 have been amended to better define the invention by pointing out that sedated state refers to a "conscious" sedated state, as described throughout the specification, *e.g.*, at ¶ 34. A replacement drawing sheet is appended hereto, which is believed to obviate the objections to Fig. 2. No new matter is added.

Information Disclosure Statement

The Office Action objects to several documents in the Information Disclosure Statements. An Information Disclosure Statement is submitted herewith, which includes a date for the Boylan publication and a copy of the Deluca publication. The Office Action objected to British Patent GB 814,278 as not being in the English language. However, this British patent is in the English language and consideration thereof is respectfully requested. The following table summarizes English language equivalents for three of the non-English references to which the Office Action objected. Consideration of each of these documents is respectfully requested.

Foreign Reference	**English Language Equivalent**
DE 3,900,941	US 5,232,551
EP 252,824	US 4,912,245
EP 365,413	US 4,946,608

Rejection Under 35 U.S.C. § 103

Claims 12, 13, and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stella U.S. Patent 6,204,257 ("Stella") in view of Lowrie et al., The Pediatric Sedation Unit: A Mechanism for Pediatric Sedation ("Lowrie"). This rejection is respectfully traversed.

As described in the specification, Stella describes the synthesis of the prodrugs of Formula I. Stella discloses the compounds can be administered in the range from 0.5 to 10 mg/kg for inducing and maintaining general anesthesia (col. 9, lines 1-25). As the Office Action acknowledges, Stella does not describe administering a bolus injection to produce a sedated state, let alone in an amount from about 2 mg/kg to less than 15 mg/kg, as claimed in claim 12.

Lowrie is cited as describing sedating children by administering propofol in a slow bolus of 1-2 mg/kg followed by a continuous infusion of 1-6 mg/kg/hr (p. 5). The Office Action asserts that, because the propofol prodrug cleaves *in vivo* to generate propofol, it would have been obvious to determine a dosage for sedating adults with the propofol prodrug based on the pediatric propofol dosages described in Lowrie. Applicants respectfully disagree.

The present inventors discovered the surprising and unexpected result that plasma propofol derived from the prodrug of Formula I is significantly more potent in suppressing EEG activity and causing a hypnotic effect than plasma propofol derived from propofol itself. As a result, bolus infusions of prodrug of Formula I are able to rapidly induce and maintain a conscious sedated state (specification, ¶¶ 27 and 29; Fig. 3).

Lowrie actually discloses a combination of a slow bolus of 1-2 mg/kg and a continuous infusion of 1-6 mg/kg/hr for sedating children (p. 5). In any event, nothing in Lowrie would have suggested that a conscious sedated status can be induced simply by administering a parenteral bolus injection of the propofol prodrug in an amount of from about 2 mg/kg to less

than 15 mg/kg, as set forth in claim 12. As described in the specification, one or more additional doses of the prodrug of Formula I may be thereafter administered as needed for maintaining the conscious sedated state.

The Office Action argues it would have been obvious to optimize the pediatric propofol doses disclosed in Lowrie for sedating adults. However, as discussed above, plasma propofol derived from bolus infusions of the prodrug of Formula I is significantly more potent and longer lasting for sedation than is plasma propofol derived from propofol itself (specification, ¶¶ 27 and 29 and Fig. 3). Therefore, the Office Action is incorrect that propofol prodrug dosages for inducing conscious sedation could have been determined based on Lowrie's disclosure involving propofol. Lowrie simply provides no guidance as to what dosages or modes of administration of the prodrug of Formula I would be effective for conscious sedation. At least for this reason, the combination of Stella and Lowrie fails to disclose or suggest the method of claim 12.

Dependent claims 13 and 36 yet further distinguish the cited prior art references. Dependent claim 13 recites that the amount of the parenteral bolus injection is from about 5 mg/kg to about 10 mg/kg. Dependent claim 36 specifies that the compound is administered in an amount of from about 5 mg/kg to about 7.5 mg/kg. Nothing in Stella or Lowrie, taken alone or in combination, suggests that parenteral bolus doses of the prodrug of Formula I in the particularly claimed amounts are effective for inducing conscious sedation. The methods of claims 13 and 36 are clearly unexpected (non-obvious) in view of the cited prior art references.

CONCLUSION

In view of the foregoing, reconsideration and withdrawal of the § 103 rejection, and allowance of the subject application, are respectfully requested. The Examiner is invited to telephone the undersigned at the number listed below if doing so would be helpful to resolve any outstanding issues.

Respectfully submitted,

BANNER & WITCOFF, LTD.

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By: /Paul M. Rivard/
Paul M. Rivard
Registration No. 43,446

Customer No. 22907
1100 13th Street N.W.
Suite 1200
Washington, D.C. 20005-4051
(202) 824-3000 (telephone)
(202) 824-3001 (facsimile)